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August 11, 2006

David Faxon, M.D. Vice-Chair, Department of Medicine Brigham and Women's Hospital 1620 Tremont Street OBC-3-12B Boston, MA 02120

Dear Dr. Faxon:

We are very pleased that you have agreed to chair the review of Dr. Aversano's revised proposal for the CPORT-II multi-state study of non-primary angioplasty.

Our primary goal is to conduct a review that is thoughtful, rigorous, fair, and efficient. The review committee for Dr. Aversano's original proposal had balance and deep expertise and conducted an outstanding review of the scientific merit of the proposal. I am therefore pleased that we – the Commission staff, Dr. Aversano, and yourself – are all in agreement that the best course of action is to ask the members of the initial review committee to review the revised proposal as well.

The questions for the review committee are straightforward:

- Does Dr. Aversano's revised proposal satisfactorily address the scientific concerns expressed in the panel's review of the original proposal?
- Is the proposed research program now scientifically sound and capable of producing reliable information to guide public policy?

The initial review also raised questions about whether the funding of the proposal would be sufficient to conduct the research. In our discussion, we agreed that, rather than ask the review committee to resolve this issue with the limited information available in

the proposal, the review committee could note this as an issue and ask the Commission staff to examine the funding issues to assure that the study can be conducted as described.

We will be pleased to provide whatever support you and the review committee need. In addition to the revised proposal and the committee's original review, I am enclosing a summary of the concerns expressed in the review of the original proposal and the ways in which the revised proposal addresses those concerns.

We thank you and the committee members for your previous service and for the excellent scientific review the panel conducted. I sincerely hope that we can count on your experience, expertise, and leadership again.

With best regards,

Rex W. Cowdry, M.D. Executive Director